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FEE TRANSMITTAL

for FY 2005

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$250.00)

Complete If Known

| | |
|----------------------|----------------------|
| Application Number | 09/816,641 |
| Filing Date | March 22, 2001 |
| First Named Inventor | Daniel Jacobs et al. |
| Examiner Name | Andrea Ragonese |
| Art Unit | 3743 |
| Attorney Docket No. | 2502000-991130 |

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____☒ Deposit Account Deposit Account Number: 07-1896 Deposit Account Name: DLA Piper Rudnick Gray Cary US LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

| Application Type | FILING FEES | | SEARCH FEES | | EXAMINATION FEES | | Fees Paid (\$) |
|------------------|-------------|-----------------------|-------------|-----------------------|------------------|-----------------------|----------------|
| | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | |
| Utility | 300 | 150 | 500 | 250 | 200 | 100 | |
| Design | 200 | 100 | 100 | 50 | 130 | 65 | |
| Plant | 200 | 100 | 300 | 150 | 160 | 80 | |
| Reissue | 300 | 150 | 500 | 250 | 600 | 300 | |
| Provisional | 200 | 100 | 0 | 0 | 0 | 0 | |

2. EXCESS CLAIM FEES

Fee Description

Each claim over 20 (including Reissues)

Each independent claim over 3 (including Reissues)

Multiple dependent claims

| | | | |
|---------------------|---------------------|-----------------|-----------------------|
| <u>Total Claims</u> | <u>Extra Claims</u> | <u>Fee (\$)</u> | <u>Fees Paid (\$)</u> |
|---------------------|---------------------|-----------------|-----------------------|

- 20 or HP = _____ x _____ = _____

HP = highest number of total claims paid for, if greater than 20

| | | | |
|----------------------|---------------------|-----------------|-----------------------|
| <u>Indep. Claims</u> | <u>Extra Claims</u> | <u>Fee (\$)</u> | <u>Fees Paid (\$)</u> |
|----------------------|---------------------|-----------------|-----------------------|

- 3 or HP = _____ x _____ = _____

HP = highest number of independent claims paid for, if greater than 3

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

| | | | | |
|---------------------|---------------------|---|-----------------|-----------------------|
| <u>Total Sheets</u> | <u>Extra Sheets</u> | <u>Number of each additional 50 or fraction thereof</u> | <u>Fee (\$)</u> | <u>Fees Paid (\$)</u> |
|---------------------|---------------------|---|-----------------|-----------------------|

- 100 = _____ /50= _____ (round up to a whole number) x _____ = _____


4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Appeal Brief (in triplicate) - sm. entity

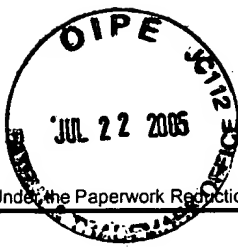
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SUBMITTED BY

| | | | |
|-------------------|---|---|------------------------|
| Signature |  | Registration No. 39,749 (Attorney/Agent) | Telephone 650-833-2433 |
| Name (Print/Type) | Alan A. Limbach | | Date July 19, 2005 |

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

46

Application Number

09/816,641

Filing Date

March 22, 2001

First Named Inventor

Daniel Jacobs et al.

Art Unit

3743

Examiner Name

Andrea Ragonese

Attorney Docket Number

2502000-991130

ENCLOSURES (Check all that apply)☒ Fee Transmittal Form☒ Fee Attached☐ Amendment/Reply☐ After Final☐ Affidavits/declaration(s)☐ Extension of Time Request☐ Express Abandonment Request☐ Information Disclosure Statement☐ Certified Copy of Priority Document(s)☐ Response to Missing Parts/
Incomplete Application☐ Response to Missing Parts
under 37 CFR 1.52 or 1.53☐ Drawing(s)☐ Licensing-related Papers☐ Petition☐ Petition to Convert to a
Provisional Application☐ Power of Attorney, Revocation
Change of Correspondence Address☐ Terminal Disclaimer☐ Request for Refund☐ CD, Number of CD(s) _____☐ Landscape Table on CD☐ After Allowance Communication to TC☐ Appeal Communication to Board
of Appeals and Interferences☒ Appeal Communication to TC
(Appeal Notice, Brief, Reply Brief)☐ Proprietary Information☐ Status Letter☒ Other Enclosure(s) (please identify
below):

1. Appeal Brief (in triplicate)

2. Return postcard

Remarks

The Commissioner is hereby authorized to charge any additional fees which
may be required or credit any overpayment to Deposit Account 07-1896. A
duplicate copy of this sheet is enclosed.

Customer No. 26379

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

DLA Piper Rudnick Gray Cary US LLP

Signature

Printed name

Alan A. Limbach

Date

July 19, 2005

Reg. No.

39,749

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July 19, 2005

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 09/816,641
Applicant : Daniel Jacobs et al.
Filed : March 22, 2001
TC/A.U. : 3743
Examiner : Andrea Ragonese
Title : TISSUE TENSION DISTRIBUTION DEVICE FOR A
COMBINED ORBITAL RIM REPAIR AND SUSPENSION
VARIATION
(as amended)

Docket No. : 2502000-991130
Customer No. : 26379

M/S Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to M/S Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on July 19, 2005.

DLA PIPER BUDNICK GRAY CARY Date: 7/19/05

By: Kathleen LaBrie

Kathleen LaBrie

APPEAL BRIEF

Sir:

This is a brief for an appeal from a Final Office Action dated January 26, 2005, an Advisory Action dated May 3, 2005, and from a Notice of Appeal filed on May 26, 2005. Three copies of this appeal brief are enclosed.

Real Party in Interest

The real party of interest is Coapt Systems, Inc., a California corporation, pursuant to the assignment executed on June 26, 2001, recorded on February 1, 2002 at reel/frame 012568/0502.

07/25/2005 MAHMED1 00000006 09816641

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Related Appeals and Interferences

There are no related appeals or interferences.

Status of Claims

Claims 1-91 were originally filed. Claims 62-74 were cancelled in response to a restriction requirement. Claims 3-7, 9-10, 14-15, 17-20, 22-23, 27-45, 51-53, 59-61 and 75-91 were subsequently cancelled by amendment. This is an appeal of the rejected claims 1-2, 8, 11-13, 16, 21, 24-26, 46-50 and 54-58. No other claims are pending or have been cancelled.

Status of Amendments

A response was filed subsequent to the final rejection, but the claims were not amended therein.

Summary of the Invention

The present invention is an implantable tissue approximation device that includes a supportive backing 408 and one or more attachment points 406 extending therefrom, as illustrated in Fig. 4B below.

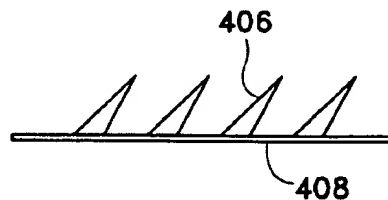


FIG. 4B

The attachment point(s) extend from the front side of the backing in a non-orthogonal manner, which ensures tissue penetration and approximation stability, and reduces tissue irritation after device installation (see specification, page 24, lines 3-16). The supportive backing includes at least one through-hole 1530 formed therethrough, which provides a means for using a fastener such as a pin or screw (see specification, page 51, lines 8-11), or an extension member 1710 (see

specification, page 55, lines 12-18), to secure the backing to tissue or bone, as illustrated in Figs. 33A and 37C/D:

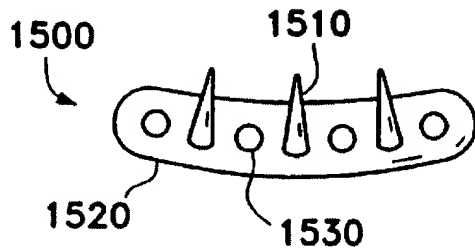
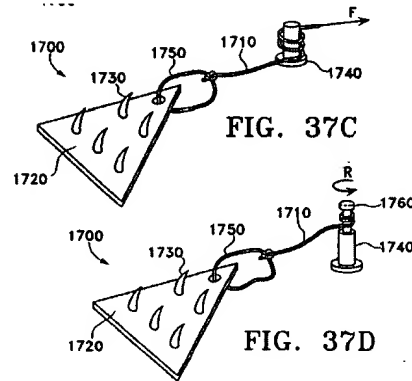
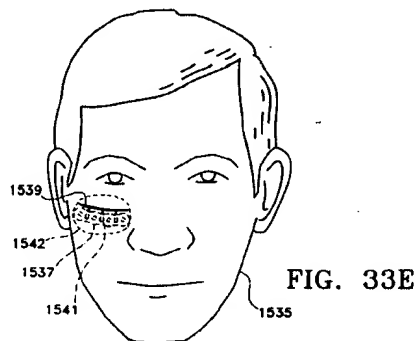


FIG. 33A



Multiple through-holes 1530 enable the backing to not only distribute tension from the tissue engaged with the tines, but can additionally be used to secure the underlying bone together, such as setting fragmented bone, as described on page 52, lines 14-17 of the specification and illustrated in Fig. 33E:



Issues

The issues on appeal are:

1. Do claims 1-2, 8, 11-13, 16, 21, 24-26, 46-50 and 54-58 fail to comply with the 35 U.S.C. §112 written description requirement by incorporating new matter into the claims.
2. Are claims 1-2, 8, 11-13, 16, 21, 24-26, 46-50 and 54-58 anticipated by or rendered unpatentable over U.S. Patent 5,352,229 (Goble), U.S. Patent 4,548,202 (Duncan), U.S. Patent 5,779,706 (Tschakaloff), and/or US Patent 6,110,100 (Talpade).

Grouping of the Claims

The claims do not stand or fall together. Applicants consider claims 1-2, 8, 11-13, 24-26, 46-47, 49, and 55-58 to be separately patentable from claims 21 and 54, and separately patentable from claims 48 and 50.

Attachments

Attached herewith please find an appendix containing the claims involved in the appeal.

Argument

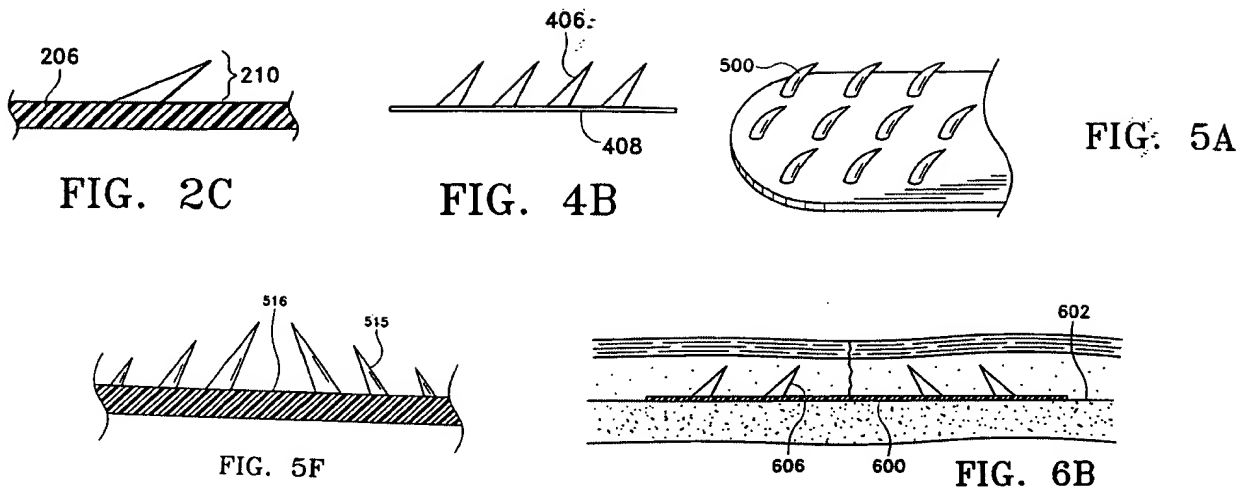
I. Rejection Under 35 U.S.C. 112

Claims 1-2, 8, 11-13, 16, 21, 24-26, 46-50 and 54-58 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement because the phrase “at least one attachment point extending from the front side of said backing in a non-orthogonal manner” lacks support in the original disclosure.

The Applicants respectfully traverse this rejection. The non-orthogonal orientation of the attachment point relative to the backing is disclosed on page 24, lines 3-16 of the specification, and is shown in various figures, all as originally filed. For example, the specification states:

“Attachment points may be canted in one direction (500), such as toward the center of the device as shown in Figure 5A. The attachment points may also be variously oriented, such as toward center (502) and erect (504), or toward center (502) and away from center (506). It is within the scope of this invention to have attachment points extending in any relative direction or orientation on the backing.” (Page 24, lines 7-12)

Moreover, Figs. 2C, 4B, 5A, 5F and 6B are just some examples of drawings as originally filed that clearly illustrate attachment points extending from the front side of the backing in a non-orthogonal manner:



Therefore, it is respectfully submitted that this rejection is erroneous and should be withdrawn.

II. Rejections Under 35 U.S.C. 102 and 103

Claims 1-2, 13, 16, 18, 21, 24-26 and 54 stand rejected under 35 U.S.C. §102(b) as being anticipated by US Patent 5,352,229 (Goble).

Claims 8, 11-12, 46-47 and 49 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Goble in view of US 4,548,202 (Duncan).

Claims 8, 46-47 and 49 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Goble in view of US Patent 5,779,706 (Tschakaloff).

Claims 48 and 50 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Goble.

Claims 55-58 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Goble in view of US Patent 6,110,100 (Talpade).

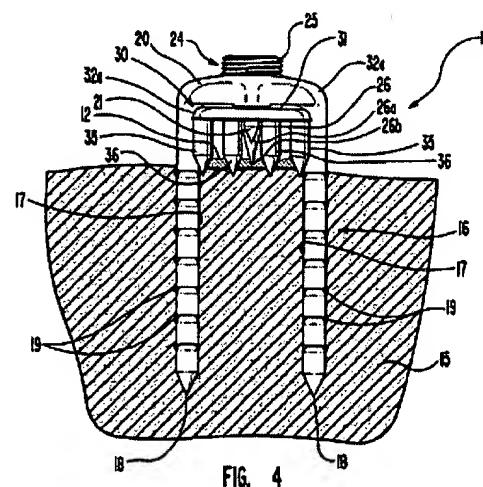
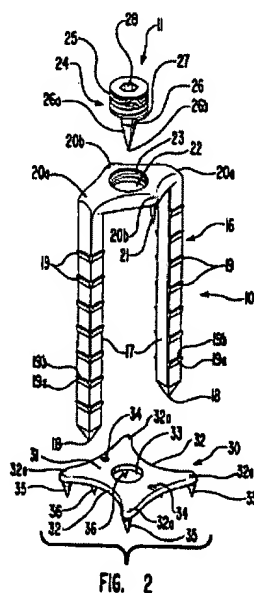
Rejection of Claims 1-2, 13, 16, 18, 21, 24-26 and 54 Under § 102(b)

Claims 1-2, 13, 16, 18, 21, 24-26 and 54 stand rejected under 35 U.S.C. §102(b) as being anticipated by US Patent 5,352,229 (Goble).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The Applicants respectfully submit that Goble fails to expressly or inherently describe each and every element of claim 1.

Claim 1 recites a supportive backing that combines at least one through-hole, and at least one attachment point extending from the front side of the backing in a non-orthogonal manner. This claimed combination combines non-orthogonally extending attachment point(s) (for improved tissue penetration and stability, and reduced tissue irritation), with through-hole(s) to secure the backing to tissue or bone (for positioning and/or bone fracture repair).

In contrast, Goble discloses an arbor press staple and washer, which includes a flat plate 31, an opening 33 formed in the plate to allow threaded pin 24 to pass there-through, and a plurality of straight spikes 35/36 (Col. 5, line 55 to Col. 6, line 28; Fig. 2) that extend from the plate 31 in an orthogonal manner so that the direction of the spikes match their movement. As the flat plate 31 is moved vertically (relative to staple 16), spikes 35/36 travel into ligament 12 and may travel into the bone surface (Col. 6, lines 46-52; Fig. 4), as shown below in Figs. 2 and 4:



The spikes 35/36 in Goble are clearly shown in the figures as extending from the bottom surface of plate 31 in an orthogonal manner (see Figs. 2, 4 and 5), and the Goble specification explicitly states that the spikes “extend at right angles” from the undersurface of the flat plate 31 (Col. 6, lines 13-17). Thus, Goble fails to anticipate claim 1. In fact, Goble teaches away from the claimed combination of claim 1 because any non-orthogonal extension of the spikes of Goble would be incompatible with the vertical movement of plate 31 as threaded pin 24 is operated.

On page 2 of the Final Office Action, the Examiner asserts that Goble does teach attachment points extending from the backing in a non-orthogonal manner:

“The attachment point 35 extends from the backing 31 in a non-orthogonal manner, since the sides of the extension to which the attachment point 35 is connected to the backing 31 project from the backing 31 as an angle to the surface from which they extend. There is no 90° angle between the side of the extension to which the attachment point 35 is connected; on the contrary, the angle is approximately 45°, which would make the ‘at least one attachment point 35 extending from the front side of said backing 31 in a non-orthogonal manner.’”

The Examiner’s explanation relies on an “extension” to which the attachment point 35 is connected to the backing. Yet, no such extension is shown in the drawings, and the term “extension” cannot be found in the Goble specification. In the Applicants’ March 24, 2005 response to the Final Office Action, it was noted that no “extension” was shown in the drawings or described in the specification of Goble, and that if the Examiner maintained this rejection, the Applicants requested that the “extension” relied upon for the rejection be identified with better specificity. In the Advisory Action issued in response thereto, the Examiner simply recited the above quoted language verbatim, with no further clarification.

The Applicants also noted that if the Examiner was somehow construing “attachment point” as limited only to the very tip of the spike, that such an interpretation would be contrary to the specification and the claims. The Applicants’ disclosure (against which the claims are construed) makes explicitly clear that “attachment points” are tines or prongs, and not just the very tip of such tines or prongs (see page 21, lines 5+). More importantly, claim 1 recites that

the attachment point extends from the front side of the backing (in an non-orthogonal manner), not from any intermediary element such as an “extension”.

Therefore, it is respectfully submitted that claim 1 (and claims 2, 13, 16, 21, 24-26 and 54 dependent thereon), are not anticipated by Goble.

It is further submitted that claims 21 and 54 are separately patentable from claims 1-2, 8, 11-13, 24-26, 46-47, 49, and 55-58 because none of the reference relied upon by the Examiner teach (or suggest) combining a plurality of non-orthogonally extending attachment points with one or more through holes disposed therebetween or interspersed therein.

It is also further submitted that claims 48 and 50 are separately patentable from claims 1-2, 8, 11-13, 24-26, 46-47, 49, and 55-58 because none of the reference relied upon by the Examiner teach (or suggest) combining a plurality of non-orthogonally extending attachment points and a through hole, with curved or concave backing front or back sides.

Rejection of Claims 8, 11-12, 46-47 and 49 Under § 103(a)

Claims 8, 11-12, 46-47 and 49 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Goble in view of US 4,548,202 (Duncan).

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); MPEP 2143.03. Further, there must be something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination. Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co., 730 F.2d 1452, 1462, 221 U.S.P.Q. 481, 488 (Fed. Cir. 1984).

Claims 8, 11-12, 46-47 and 49 all depend from claim 1, which is considered allowable for the reasons set forth above. The addition of Duncan fails to remedy the deficiencies of Goble. Specifically, the combination of Goble and Duncan fails to teach or suggest the claim limitations of these rejected claims.

Additionally, the prior art references fail to suggest the desirability of making the claimed combination of elements. The text citations from Duncan relied upon by the Examiner regarding “facilitating healing”, “hemostatic compression”, and accommodating “varying tissue thicknesses” fail to teach or suggest flexibility, porosity, the use of mesh, net, or lattice, biodegradable/biological materials, or intra-operative shaping as recited in dependent claims 8, 11, 12, 46, 47 and 19. More importantly, one having ordinary skill in the art would not modify the device in Goble to make it flexible, make it porous, make it out of mesh, net or lattice, or make it for intra-operative shaping as suggested by the Examiner, because the Goble device relies on the rigidity of plate 31 so that threaded pin 24 can spikes 35/36 through the ligament and on the bone surface (Col. 6, lines 46+). A primary reference may not be modified in light of or combined with one or more secondary references where the result would be to render the primary reference inoperable for its intended purpose. In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). Therefore, the Applicants respectfully traverse the conclusion that it would have been obvious to modify the Goble device as stated by the Examiner.

Rejection of Claims 8, 46-47 and 49 Under § 103(a)

Claims 8, 46-47 and 49 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Goble in view of US Patent 5,779,706 (Tschakaloff).

Claims 8, 46-47 and 49 depend from claim 1, which is considered allowable for the reasons set forth above. The addition of Tschakaloff fails to remedy the deficiencies of Goble (i.e. the combination of Goble and Tschakaloff fails to teach or suggest the claim limitations of these rejected claims). Additionally, as stated above, it would not have been obvious to modify the Goble device in a manner that would render it inoperative for its intended purpose, which is the necessary result of combining Tschakaloff with Goble.

Rejection of Claims 48 and 50 Under § 103(a)

Claims 48 and 50 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Goble.

Claims 48 and 50 depend from claim 1, which is considered allowable for the reasons set forth above. Moreover, claims 48 and 50 recite that the supportive backing front and back sides are curved or the back side is concave. The Examiner acknowledges that Goble fails to teach or suggest any such configuration of the backing. Instead, the Examiner premises this rejection on a general conclusion that it was well known to form implant devices in a curved configuration and thus it would have been obvious to so modify the backing. First, deficiencies in the factual basis cannot be supplied by resorting to speculation or unsupported generalities. In re Warner, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967). Secondly, such reliance on what is allegedly well known fails to establish the requisite motivation for combining it with Goble. Thus, it is improper to rely on the stated general conclusion about allegedly known curved implant device configurations. Moreover, MPEP §2144.03 states that while Examiners may take official notice of facts outside of the record, if the applicant traverses such an assertion, "the examiner should cite a reference in support of his or her position". To the extent the Examiner is taking official notice of curved implant devices, and/or of the motivation to combine, the Applicants have specifically traversed this position, and received no cited references to support such a position in response.

The Examiner also premises this rejection on a conclusion that the Applicants have not asserted that this specific configuration provides an advantage, solves a problem or serves a purpose different from a planar backing. To the contrary, page 52, lines 12-13 of the disclosure explicitly states that such devices are well suited for orbital reconstruction and suspensions where curves are desirable to accommodate facial bones.

Therefore, it is submitted claims 48 and 50 are not rendered obvious by Goble.

Rejection of Claims 55-58 Under § 103(a)

Claims 55-58 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Goble in view of US Patent 6,110,100 (Talpade).


Claims 55-58 depend from claim 1, which is considered allowable for the reasons set forth in Part 3 above. The addition of Talpade fails to remedy the deficiencies of Goble.

Conclusion

For all of these reasons, Applicants respectfully submit that the rejections based upon 35 U.S.C. 112, 102 and 103 are in error and request the Board to affirm the patentability of the claims on appeal.

Respectfully submitted,

DLA PIPER RUDNICK GRAY CARY US LLP

Dated: July 19, 2005 By: 
Alan A. Limbach
Reg. No. 39,749

Attorneys for Applicant(s)

Alan A. Limbach
DLA Piper Rudnick Gray Cary US LLP
2000 University Avenue
East Palo Alto, CA 94303-2248
650-833-2433 (Direct)
650-833-2000 (Main)
650-833-2001 (Facsimile)
alan.limbach@dlapiper.com

APPENDIX

1. An implantable tissue approximation device comprising:
a supportive backing having a front side, a back side, and at least one through-hole formed therethrough; and
at least one attachment point extending from the front side of said backing in a non-orthogonal manner.
2. The tissue approximation device of claim 1 wherein said backing has a shape in the form of a character selected from the group consisting of C, H, I, L, T, U, V, Δ , and \cap
8. The tissue approximation device of claim 1 wherein said backing is configured to be flexible.
11. The tissue approximation device of claim 1 wherein said backing comprises porous material.
12. The tissue approximation device of claim 11 wherein said porous material comprises a mesh, net, or lattice.
13. The tissue approximation device of claim 1 wherein said backing comprises a solid material.
16. The tissue approximation device of claim 1 wherein said at least one attachment point includes a shape and direction selected from the group consisting of canted tines, erect tines, canted hooks, canted arrowheads, erect barbed tipped tines, canted barbed tipped tines, erect arrowhead tipped tines, canted arrowhead tipped tines, erect nail-shaped tines, canted nail-shaped tines, and cheese grater-like tines.

21. The tissue approximation device of claim 1 wherein the at least one attachment point includes a plurality of attachment points, and wherein the at least one through-hole is disposed between the attachment points.

24. The tissue approximation device of claim 1 wherein the supportive backing is rigid.

25. The tissue approximation device of claim 24 wherein the supportive backing has a strength sufficient to set fragmented bones.

26. The tissue approximation device of claim 1 wherein the at least one through hole includes a plurality of through-holes formed through the supportive backing.

46. The tissue approximation device of claim 1 wherein said device comprises a material selected from the group consisting of biodegradable and biological materials.

47. The tissue approximation device of claim 46 wherein said biological material comprises one or more materials selected from the group consisting of collagen, hydroxyapatite from natural sources, hydroxyapatite from synthetic sources, bone graft, and any polymerized versions or composites thereof.

48. The tissue approximation device of claim 1 wherein said front and back sides are curved.

49. The tissue approximation device of claim 1 wherein said device is configured such that it is shapeable intra-operatively for use in a patient's body.

50. The tissue approximation device of claim 1 wherein said back side of said backing is concave.

54. The tissue approximation device of claim 26 wherein said at least one attachment point includes a plurality of attachment points that are interspersed among the plurality of through-holes.

55. The tissue approximation device of claim 1 wherein said device comprises at least one therapeutic agent.

56. The tissue approximation device of claim 55 wherein said device is impregnated with said at least one therapeutic agent.

57. The tissue approximation device of claim 55 wherein said device is coated with said at least one therapeutic agent.

58. The tissue approximation device of claim 57 wherein said at least one therapeutic agent is selected from the group consisting of proteins, pharmaceuticals, genetic material.